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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,366		REGINA RESZKA	2936.169/00	7163

7590

03/27/2002

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EXAMINER

SCHMIDT, MARY M

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/27/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/581,366		RESZKA, REGINA	
	Examiner		Art Unit	
	Mary Schmidt		1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 34-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 and 34-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The amendment filed 1/03/02 was entered. Claims 1-24 and 34-46 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-24 and 34-46, drawn to agents comprising (a) one or more genetic materials, (b) liposomes consisting of **PEG-liposomes**, c) a drug carrier embolization system (DCES), and (d) a contrasting agent.

Group II, claim(s) 1-24 and 34-46, drawn to agents comprising (a) one or more genetic materials, (b) liposomes consisting of **immuno-liposomes**, c) a drug carrier embolization system (DCES), and (d) a contrasting agent.

Group III, claim(s) 1-24 and 34-46, drawn to agents comprising (a) one or more genetic materials, (b) liposomes consisting of **cationic liposomes**, c) a drug carrier embolization system (DCES), and (d) a contrasting agent.

Group IV, claim(s) 1-24 and 34-46, drawn to agents comprising (a) one or more genetic materials, (b) liposomes consisting of **polymer-modified liposomes**, c) a drug carrier embolization system (DCES), and (d) a contrasting agent.

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3. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 is broadly drawn to agents for effecting gene transfer, comprising (a) one or more genetic elements, (b) liposomes chosen from the group consisting of PEG-liposomes, immuno-liposomes, immuno/PEG-liposomes, cationic liposomes, and polymer-liposomes, c) drug carriers and (d) contrasting agents. The claims thus comprise multiple products.

Each of the claimed types of liposomes in claim 1 (part (b)) are known in the art to be divergent in structure and methods of making for instance. (See WO 96/08235, WO 97/46671, WO97/13501 and WO 94/22468 which illustrate known types of liposomes for different uses)

The prior art taught at the time the invention was made the use of drug embolization systems and contrasting agents in liposomes comprising genetic materials. See for instance WO 95/03035 which taught use of polymerizing agents for improved oral delivery and WO 96/11023 which taught gadolinium as a contrasting agent.

Since the combination of the elements of parts (a), c) and (d) considered as a whole with each of the different types of liposomes of part (b) does not make a contribution over the prior art, the claims do not share a "special technical feature" that defines a contribution made by the claim as a whole over said prior art. As such, the fact that the multiple products were claimed in part (b) of claim 1 which are not considered equivalents, the above restriction is considered proper.

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4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.



JOHN L. LeGUYADER
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TECHNOLOGY CENTER 1600

M. M. Schmidt
March 25, 2002